

NEW ZEALAND CONSUMER MEDICINE INFORMATION

MONTELUKAST MYLAN

montelukast sodium 4 mg and 5 mg chewable tablet

montelukast sodium 10 mg film coated tablet



What is in this leaflet

Please read this leaflet carefully before you start taking MONTELUKAST MYLAN.

This leaflet answers some common questions about MONTELUKAST MYLAN.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking MONTELUKAST MYLAN against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What MONTELUKAST MYLAN is used for

MONTELUKAST MYLAN is used to treat:

- asthma, including preventing asthma symptoms during the day and night. It also prevents the narrowing of airways triggered by exercise.
- seasonal and year-round allergies, including daytime and night time symptoms, including nasal congestion, runny nose, nasal itching, and sneezing; nasal congestion upon awakening, difficulty going to sleep, and night time awakenings; tearing, itchy, red, and puffy eyes.

MONTELUKAST MYLAN can be used in children 2 years of age and older, teenagers and adults.

MONTELUKAST MYLAN tablets are not used to treat an acute attack of asthma. If an acute attack occurs, follow your doctor's instructions for that situation.

Asthma is a lung disease and has the following characteristics:

- narrowed airways causing breathing to become difficult.
- inflamed airways, which means the lining of airways become swollen.
- sensitive airways that react to many things, such as cigarette smoke, pollen, or cold air.

Symptoms of asthma include coughing, wheezing and chest tightness. Not all people with asthma wheeze. For some, coughing may be the only symptom of asthma. Symptoms often occur during the night or after exercise.

Seasonal allergies (also known as hay fever) are triggered by outdoor allergens such as airborne pollens from trees, grasses and weeds.

Year-round allergies may occur year-round and are generally triggered by indoor allergens such as dust mites, animal dander, and/or mould spores.

The daytime and night time symptoms of allergies typically may include:

- stuffy, runny, itchy nose,
- sneezing,
- watery, swollen, red, itchy eyes.

MONTELUKAST MYLAN belongs to a group of medicines called leukotriene receptor antagonists. It works by blocking substances in your lungs called leukotrienes that cause narrowing and swelling of airways. Blocking leukotrienes improves asthma

symptoms and helps prevent asthma attacks. Leukotrienes also cause allergy symptoms. Blocking leukotrienes improves allergic rhinitis (seasonal and year-round, also known as outdoor and indoor nasal allergies).

Your doctor may have prescribed this medicine for another reason.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

This medicine is available only with a doctor's prescription.

This medicine is not addictive.

Before you take MONTELUKAST MYLAN

When you must not take it

Do not take MONTELUKAST MYLAN if you have an allergy to:

- any medicine containing montelukast sodium.
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include: shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not give this medicine to a child under the age of 2 years.

Safety and effectiveness in children younger than 2 years have not been established.

- 10 mg tablets are recommended for adults

and teenagers 15 years and older

- 5 mg chewable tablets are recommended for children 6-14 years old
- 4 mg chewable tablets are recommended for children 2-5 years old

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Montelukast Mylan chewable tablets contains aspartame.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding. MONTELUKAST MYLAN has not been studied in pregnant women and it is not known if this medicine passes into breast milk. Your doctor can discuss with you the risks and benefits involved.

Tell your doctor if you have liver disease.

If you have not told your doctor about any of the above, tell them before you start taking MONTELUKAST MYLAN.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop.

You should also tell any health professional who is prescribing a new medication for you that you are taking MONTELUKAST MYLAN.

Some medicines may interfere with MONTELUKAST MYLAN. These include:

- phenytoin (used for treatment of epilepsy)
- phenobarbital (used for treatment of epilepsy)
- rifampicin (used to treat tuberculosis and some other infections)
- gemfibrozil (used for treatment of high lipid levels in plasma).

These medicines may be affected by MONTELUKAST MYLAN or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take MONTELUKAST MYLAN

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

Take MONTELUKAST MYLAN only when prescribed by your doctor.

For adults and teenagers 15 years and older, for the treatment of asthma, seasonal and year-round allergies, the dose is one 10 mg tablet taken daily.

For children 6 to 14 years old, for the treatment of asthma, seasonal and year-round allergies, the dose is one 5 mg chewable tablet taken daily.

For children 2 to 5 years old, for the treatment of asthma, seasonal and year-round allergies, the dose is one 4 mg chewable tablet taken daily.

Studies have shown that MONTELUKAST MYLAN does not affect the growth rate of children.

How to take it

MONTELUKAST MYLAN comes as three types of tablets:

- 10 mg tablets for adults and teenagers 15 years and older
- 5 mg chewable tablets for children 6-14 years old
- 4 mg chewable tablets for children 2-5 years old

Swallow the 10 mg tablet whole with a glass of water.

Chew the 4 mg or 5 mg chewable tablet thoroughly and swallow.

When to take it

For patients with asthma, take MONTELUKAST MYLAN once a day in the evening. Taking your tablet at bedtime each day will have the best effect. It will also help you remember when to take the tablets.

For patients with allergic rhinitis, take MONTELUKAST MYLAN once a day as prescribed by your doctor. Taking it at the same time each day will help have the best effect. It will also help you remember when to take it.

MONTELUKAST MYLAN **chewable tablets** should be taken on an empty stomach, for example, 1 hour before food or 2 hours after food. Food can interfere with the absorption of this medicine.

MONTELUKAST MYLAN film coated tablets can be taken with or without food.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition but does not cure it. It is important to keep taking your MONTELUKAST MYLAN

If you forget to take it

Skip the dose you missed and take your next dose as usual.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

While you are taking MONTELUKAST MYLAN

Things you must do

Continue taking MONTELUKAST MYLAN every day as directed by your doctor, even if you have no asthma symptoms or if you have an asthma attack.

If your or your child's asthma gets worse while taking MONTELUKAST MYLAN, tell your doctor immediately.

If an acute attack of asthma occurs, follow your or your child's doctor's instructions on what medicines to use to relieve the attack.

If you or your child experience behaviour and mood-related changes while taking MONTELUKAST MYLAN, tell your doctor immediately.

If you or your child is on anti-asthma medicines, be aware that if he/she develops a combination of symptoms such as flu-like illness, pins and needles or numbness of arms or legs, worsening of pulmonary symptoms, and/or rash, you should consult your doctor.

If you become pregnant while taking MONTELUKAST MYLAN, tell your doctor immediately.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking MONTELUKAST MYLAN.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.

Keep all of your doctor's appointments so that your progress can be checked.

Things you must not do

Do not take MONTELUKAST MYLAN to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how MONTELUKAST MYLAN affects you. This medicine may cause drowsiness or dizziness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous. Children should be careful when riding bicycles or climbing trees

Be careful when drinking alcohol while you are taking this medicine. If you drink alcohol, drowsiness or dizziness may be worse.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766) or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much MONTELUKAST MYLAN. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Symptoms of an overdose may include:

- abdominal pain,
- sleepiness or drowsiness,
- thirst,
- headache,
- vomiting,
- hyperactivity.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking MONTELUKAST MYLAN.

This medicine helps most people, but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- headache,
- stomach pain,
- thirst,
- bedwetting in children,
- weakness/tiredness,
- diarrhoea,
- an uncomfortable feeling in the stomach or belching after eating,
- indigestion,
- nausea or vomiting,
- dry mouth,
- dizziness, drowsiness,
- pins and needles/numbness,
- nose bleed;
- bruising,
- joint pain, muscle aches or muscle cramps,
- feeling weak or a lack of energy,
- restlessness,
- tremor,
- strange dreams including nightmares,
- trouble sleeping (insomnia),
- disorientation,
- irritability,
- stuttering.

Tell your doctor as soon as possible if you notice any of the following:

- upper respiratory infection, symptoms may include coughing, nasal congestion, runny nose, excess mucus or scratchy sore throat,

- bleeding or bruising more easily than normal,
- behaviour and mood related changes including agitation including aggressive behaviour or hostility, depression,
- hyperactivity,
- disturbances in attention,
- feeling anxious,
- hallucinations,
- trouble remembering (memory impairment),
- obsessive-compulsive symptoms,
- sleep walking,
- uncontrolled muscle movements,
- symptoms of liver disease which includes nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, light coloured bowel motions, and dark coloured urine,
- swelling of hands, ankles, feet or other body parts due to fluid build-up,
- fever,
- tender red lumps under the skin, most commonly on your shins (erythema nodosum).

Tell your doctor immediately if have suicidal thoughts and actions

The above list includes serious side effects that may require medical attention.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- palpitations,
- seizures,
- swelling (inflammation) of the lungs,
- allergic reactions:
 - including swelling of the face, lips, tongue, and/or throat (which may cause trouble breathing or swallowing),
 - hives (severe and sudden onset of pinkish itchy swellings on the skin, also called nettle rash),
- severe skin reactions that may occur without warning such as rash, and itching,
- rash on the body where each mark resembles a bull's eye,

- chest pain,
- shortness of breath,
- rapid breathing or wheezing,
- combination of symptoms such as flu-like illness, pins and needles or numbness of arms and legs, worsening of pulmonary symptoms and/or rash (Churg-Strauss syndrome).

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After taking MONTELUKAST MYLAN

Storage

Keep your tablets in the bottle until it is time to take them.

If you take the tablets out of the pack they may not keep well.

Keep your tablets in a cool dry dark place where the temperature stays below 25°C.

Do not store MONTELUKAST MYLAN or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your

pharmacist what to do with any medicine that is left over.

Product description

What it looks like

4 mg chewable tablet: A white to off-white coloured, oval, biconvex tablet debossed with "M" on one side and "MS1" on the other side.

5 mg chewable tablet: A white to off-white coloured, round, biconvex tablet debossed with "M" on one side and "MS2" on the other side.

10 mg film coated tablet: A blue film-coated, round bi-convex beveled edge shaped tablet debossed with "MO" over "10" on one side and "M" on the reverse.

Ingredients

Active ingredient(s):

- MONTELUKAST MYLAN 4 mg chewable tablet contains montelukast sodium which corresponds to 4 mg montelukast.
- MONTELUKAST MYLAN 5 mg chewable tablet contains montelukast sodium which corresponds to 5 mg montelukast.
- MONTELUKAST MYLAN 10 mg film coated tablet contains montelukast sodium which corresponds to 10 mg montelukast.

Inactive ingredient(s):

MONTELUKAST MYLAN 4 mg and 5 mg chewable tablets also contains:

- mannitol,
- microcrystalline cellulose,
- croscarmellose sodium,
- aspartame (E951),
- colloidal anhydrous silica,
- magnesium stearate,
- sodium lauryl sulfate,
- The cherry flavour (501027 AP 0551) contains:
 - maize maltodextrin,
 - benzyl alcohol (E1519),
 - triethyl citrate (E1505).

MONTELUKAST MYLAN 10 mg film coated tablets also contains:

- microcrystalline cellulose,

- mannitol,
- croscarmellose sodium,
- magnesium stearate,
- sodium laurylsulfate
- silica colloidal anhydrous.
- The film coating consists of:
 - polydextrose,
 - titanium dioxide,
 - hypromellose,
 - triacetin,
 - indigo carmine aluminium lake (E132),
 - macrogol 400,
 - sunset yellow aluminium lake (E110),
 - macrogol 8000.

This medicine does not contain lactose or gluten.

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

MONTELUKAST MYLAN is supplied in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11183,
Ellerslie,
Auckland
NEW ZEALAND

Telephone: (09) 579 2792

Date of Preparation

24 August 2020
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